SPINE WAVE

510(k) Summary
StaXx® System

DEC 0 6 2013

1. Submitter Information

Submitter: Spine Wave, Inc.
Address: Three Enterprise Drive
Suite 210
Shelton, CT 06484
Telephone: 203-712-1847
Telefax: 203-944-9493

Contact: Joseph Mercado

Date Prepared: December 3, 2013

2. Device Information

Trade Name: StaXx® System

Common Name(s): Vertebral Body Replacement; Intervertebral Body Fusion Device

Classification Name(s): Spinal Intervertebral Body Fixation Orthosis; Intervertebral Fusion Device with Bone Graft, Lumbar

Classification(s)/Code(s): Class II per 21 CFR 888.3060/MQP; Class II (special controls) per 21 CFR 888.3080/MAX

3. Purpose of Submission

The purpose of this submission is to gain clearance for a new Surgical Gun to be used with the StaXx® Systems.

4. Predicate Device Information

The StaXx® Systems described in this submission are substantially equivalent to the following predicates:

Predicate Device	Manufacturer	Most recent 510(k) No.
StaXx® XD System	Spine Wave, Inc.	K121889
StaXx® XDL System	Spine Wave, Inc.	K102315
StaXx® IB System	Spine Wave, Inc.	K123461
StaXx® IBL System	Spine Wave, Inc.	K132719

5. Device Description

The StaXx® Systems are composed of expandable implants and interlocking wafers, which are implanted through a delivery system that includes a Cartridge and a Surgical Gun. The Cartridge is inserted into the Surgical Gun which, when activated, sequentially delivers locking wafers from the Cartridge to the expandable implant. The wafers are designed to be inserted incrementally to form a stack and therefore attain the desired height.

The StaXx® XD and XDL Systems are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5). They are composed of wafers that are stacked into an expandable implant to replace and restore height of a collapsed, damaged, or unstable vertebral body or portion thereof, due to tumor or trauma (i.e., fracture). The implant components are manufactured from PEEK-OPTIMA with 6% Barium Sulfate and contain tantalum markets for additional visualization under fluoroscopy. The StaXx® XD System is to be placed bilaterally while the StaXx® XDL System is to be placed unilaterally and both are to be used with autograft or allograft and supplemental spinal fixation. The supplemental fixation system that is intended to be used with the StaXx® XD System is the CapSure® PS Spine System.

The StaXx® IB and IBL Systems are intervertebral body fusion devices composed of wafers that are stacked into an expandable implant to adjust the height of the implant. The implants are to be used with autogenous bone graft material. The StaXx® IB implant components are manufactured from both PEEK-OPTIMA and PEEK-OPTIMA with 6% Barium Sulfate while the StaXx® IBL implant components are manufactured from PEEK-OPTIMA with 6% Barium Sulfate and tantalum markers.

6. Intended Use

The StaXx® Systems have the following indications:

The StaXx® XD System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace and restore height of a collapsed, damaged, or unstable vertebral body or portion thereof, due to tumor or trauma (i.e., fracture). The system is to be placed bilaterally and used with autograft or allograft and supplemental spinal fixation. The supplemental fixation system that is intended to be used with the StaXx® XD System is the CapSure® PS Spine System.

The StaXx® XDL System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace and restore height of a collapsed, damaged, or unstable vertebral body or portion thereof, due to tumor or trauma (i.e., fracture). The system is to be used with autograft or allograft and supplemental spinal fixation.

The StaXx® IB System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The StaXx® IB System is to be used with autogenous bone graft and with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

The StaXx® IBL System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-L5. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The StaXx® IBL System is to be used with autogenous bone graft and with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

7. Comparison of Technological Characteristics

The substantial equivalence of the StaXx® Systems to the predicates is shown by similarity in intended use, indications for use, materials and performance.

8. Performance Data

The following non-clinical tests were performed to demonstrate that the subject StaXx® Systems are substantially equivalent to the listed predicate devices:

- Simulated Use Testing
- Insertion Testing
- Cadaveric Testing

9. Conclusion

Based on the indications for use, technological characteristics and comparison to the predicates, the subject StaXx® Systems have been shown to be substantially equivalent to the predicate devices identified in this submission, and do not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Spine Wave, Incorporated
Mr. Joseph Mercado
Regulatory Affairs Specialist
3 Enterprise Drive, Suite 210
Shelton, Connecticut 06484

Re: K133207
Trade/Device Name: StaXx® Surgical Gun
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP, MAX
Dated: November 5, 2013
Received: November 6, 2013

Dear Mr. Mercado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133207

Device Name
StaXx(R) Surgical Gun

Indications for Use *(Describe)*
The StaXx® Systems have the following indications:

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The StaXx® XDL System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace and restore height of a collapsed, damaged, or unstable vertebral body or portion thereof, due to tumor or trauma (i.e., fracture). The system is to be used with autograft or allograft and supplemental spinal fixation.

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The StaXx® IBL System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-L5. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The StaXx® IBL System is to be used with autogenous bone graft and with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices